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February 12, 2020

**VIA ECF**

Honorable Joel Schneider  
United States Magistrate Judge  
U.S. District Court - District of New Jersey  
Mitchell S. Cohen Building & US Courthouse  
1 John F. Gerry Plaza, Courtroom 3C  
4th and Cooper Streets  
Camden, New Jersey 08101

Re: IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION  
Civil No. 19-2875 (RBK/JS)

Dear Judge Schneider:

Please accept this letter on behalf of Plaintiffs addressing the issues to be discussed during the February 13, 2020 status conference.

**1. Downstream Defendant Discovery**

Plaintiffs sent narrowly tailored proposed discovery requests to Wholesaler and Retailer/Dispensing Defendants on January 24, which explicitly incorporated certain requests proposed by these Defendants themselves and offered to meet with Defendants to answer any questions. Plaintiffs reached out again to these Defendants on February 4 and 6 offering to answer any questions and requesting a meet and confer. On February 6, these Defendants sent a series of

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questions about the requests to Plaintiffs. Plaintiffs responded on February 11. The parties met and conferred on February 12. Plaintiffs anticipate that, as with the document requests to the Manufacturer Defendants, any requests that cannot be agreed to by the parties will be ripe for argument and decision by the next in-person CMC.

**2. Related Actions Pending Outside the MDL**

Plaintiffs expect all Losartan and Irbesartan cases to be transferred to this Court in accordance with the JMPL's order.

**3. Improperly Filed Short Form Complaints**

Plaintiffs will address any valid issues that Defendants raise regarding their Short Form Complaints.

**4. Overidentification of Defendants in Short Form Complaints**

Plaintiffs are not familiar with Defendants' issue regarding overidentification of Defendants in Short Form Complaints but remain ready to address any valid issues raised by Defendants.

**5. Plaintiff Fact Sheets**

Plaintiffs have begun to file their Fact Sheets in accordance with the Court's order. Plaintiffs will address any valid issues that Defendants raise regarding their Fact Sheets.

**6. Direct Filing Order for Losartan and Irbesartan Cases**

The Parties are discussing a proposed Direct Filing Order taking into consideration the discussion with the Court at the most recent Case Management Conference ("CMC") on January 28, 2020.

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**7. Substituting Defendants in Master Economic Complaint**

At the last CMC, a small handful of defendants named in the Master Personal Injury and Medical Monitoring Complaints, but not in the Economic Loss Complaint, asked to be formally added to the latter. The Court told the parties to agree to this by stipulation. On February 3, Plaintiffs sent Defendants a proposed stipulation to substitute the pertinent defendants for “John Doe” defendants. On February 10, Defendants indicated they believed substitution was insufficient, and insisted on a formal amended complaint. While Plaintiffs disagree, they are working on a proposed amended complaint that will be filed without prejudice to any further rights to amend the complaint as a result of such amendment.

**8. Default Against Aurobindo Pharma Pursuant to Article 15 of the Hague Convention**

On February 6, 2020, Plaintiffs filed a letter explaining why the Court should enter default against Aurobindo Pharma Limited (“Aurobindo Pharma”). To summarize, Article 15 of the Hague Convention allows the Court to enter default against a foreign defendant six months after the transmittal of the complaint, summons, and other required documents to the Central Authority of the relevant country, in this case India. Plaintiffs transmitted these documents to India’s Central Authority on May 31, 2019. Aurobindo Pharma was thus in default as of December 1, 2019. The Court should consequently enter default against Aurobindo Pharma, and allow Plaintiffs leave to request entry of a default judgment without further motion pursuant to Rule 55(b).

**9. Entry of Hetero Drugs and Hetero Labs**

Hetero Labs and Hetero Drugs (“Hetero”), the Indian API and Finished Dose Manufacturers, entered an appearance on February 6, 2020. Plaintiffs have provided Counsel for Hetero with copies of the Court’s Core Discovery Order, Macro Discovery Order, and Substantive

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Discovery Order (attaching the final Requests for Production, custodians, and search terms). Plaintiffs have further provided Hetero with information regarding certain items delineated in the Court's Core Discovery Order which were not produced by the U.S. Entities (Hetero USA and Camber), including: all inspection related documents (EIRs, 483s, correspondence and Warning Letters), a DMF file submitted to the FDA for Valsartan ("Process II"), and any communications not in the possession of the US Entities with the FDA regarding the contamination and the recall. Hetero has indicated that it would begin the process of collecting documents, with these non-duplicative categories of documents taking priority, such that these still outstanding items of Core Discovery can be produced in short order. Plaintiffs note that the EIRs are especially important in terms of identifying potential custodians.

**10. Identities of All Third Parties and/or Consultants with Authority to Communicate with the FDA on Behalf of Defendants**

During the January CMC, the Court indicated it would order the Manufacturer Defendants to identify all third-party entities (including consultants or law firms) that have been given express authority to communicate with the FDA. *See* January 28, 2020 Tr. at 112:15-18 ("I can't see why would there be an objection [to the production of third parties given approval to communicate on behalf of the Defendants with the FDA]. Their names are going to be in the communications that are product anyway so I'll include that in an order.") However, the Court's order following the CMC (D.E. 360), did not address Plaintiffs' request, and only addressed Defendants' request for an extension of the 7-day production requirement of Core Discovery. Plaintiffs ask the Court to issue an order requiring the Defendants to provide this information to Plaintiffs on or before February 24, 2020, such that Plaintiffs have this information, which is needed to ascertain whether Defendants are complying with their obligations under Core Discovery.

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Thank you for your courtesies and consideration.

Respectfully,

A handwritten signature in purple ink, appearing to read "Adam M. Slater", written over a horizontal line.

Adam M. Slater